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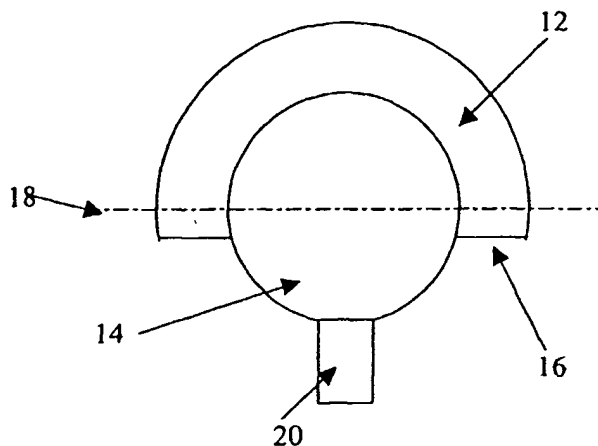
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(54) Title: **IMPROVED ACETABULAR COMPONENTS THAT DECREASE RISKS OF DISLOCATION**



(57) Abstract: The present invention provides monopolar acetabular liners that can enclose a femoral head to form a hip replacement prosthesis, wherein the liner has a rim that creates an orifice, wherein the orifice has a diameter that is smaller than the diameter of the femoral head, and wherein the liner encompasses greater than 50 percent of the volume of the head, wherein a constraining ring can be used in conjunction with the monopolar constrained acetabular liner to provide additional support for the femoral head to stay with the acetabular liner and avoid dislocation. Assemblies, complete prosthetic replacements,

and methods of replacing also are provided. Liners and constraining rings having no, one or more recesses also are provided.

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5 **IMPROVED ACETABULAR COMPONENTS THAT DECREASE RISKS OF**
6 **DISLOCATION**

7 This application claims priority to U.S. Serial No. 60/222,049 filed July
8 31, 2000, U.S. Serial No. 60/234,345 filed September 22, 2000, and U.S. Serial
9 No. 60/289,528 filed May 9, 2001, which are incorporated by reference.

10 The present invention relates to improved acetabular components, such
11 as liners, assemblies and complete replacements, for use in the body. The
12 improved acetabular components can be used, for example, in hip arthroplasties
13 in both a primary and revision setting. The present invention provides a
14 decreased risk of dislocation while facilitating greater range of motion
15 ("ROM").

16 **Description of the Field**
17

18 Dislocation is a major source of morbidity at re-operation after total hip
19 arthroplasty. Dislocation rates have been quoted at 1 - 10% for primary total
20 hip arthroplasties. Many studies have shown increased rates of dislocation after
21 revision total hip arthroplasty when compared with primary total hip
22 arthroplasty. Currently, the chance of "successful surgical management of a
23 recurrent dislocation" is 70% when a cause for the dislocation can be identified.
24 Dislocation results in significant patient anxiety. In addition, the costs
25 associated with surgical management of dislocation are significant.

26 A variety of approaches have been used to address dislocation, including
27 changing the angle of the femoral component, changing the angle of the
28 acetabular component, using extended lip liners, using off-set liners, advancing

1 the greater trochanter, and using constrained acetabular components. Another
2 approach is to use femoral heads of larger diameter.

3 Some of these approaches have distinct disadvantages, however.
4 Altering the orientation of the components can increase stability in one
5 direction (for example, posteriorly) but at the same time decrease stability in the
6 opposite direction (for example, anteriorly). Use of extended lip liners and
7 currently available constrained acetabular components which utilize additional
8 polyethylene to surround the femoral head increases joint stability but this
9 additional material also can, depending on the design, constrict the range of
10 motion of the joint and can lead to subsequent problems related to
11 impingement. When the hip joint is articulated (for example, flexed, extended,
12 rotated, etc.) to its limit, impingement between the femoral neck and acetabular
13 liner may occur.

14 Component impingement is undesirable for several reasons. The
15 femoral neck impinging against the polyethylene liner can produce damage to
16 the polyethylene as well as increasing the stresses at the component / bone
17 interface. Additionally, the point of impingement acts as the fulcrum through
18 which the force produced by the leg could lever the femoral head out of the
19 liner and hence lead to dislocation.

20 Many current methods of reducing the risk of dislocation, including
21 recurrent dislocation, employ the use of so called "constrained liners," which
22 are complex bipolar or tripolar articulations. In a study of twenty one
23 constrained acetabular components to treat preoperative or intraoperative
24 instability, six patients had recurrent dislocations. It was postulated that this
25 increase was caused by the impingement of the femoral stem on the rim of the
26 insert due to decreased range of motion within the design. Orthopaedic
27 Knowledge Update, Chapter 38, page 474 (James H. Beatty, M.D., editor,
28 AAOS).

1 Constrained systems that are currently available use ultra high molecular
2 weight polyethylene (UHMWPE) which is not crosslinked. A major limitation
3 of the material is it's high wear rate and the risk of periprosthetic osteolysis.
4 Also, their stated range of motion in flexion is between 72° and 90°. Such
5 devices are available from Zimmer, Inc., Johnson & Johnson/Depuy Inc., and
6 Howmedica-Osteonics, Inc.

7 The current products have additional limitations. For example, the
8 Osteonics system utilizes only 22, 26 and 28 mm heads. The minimum
9 diameter of the acetabular shell is 50 mm. This design is "bipolar." A bipolar
10 system is made up of a acetabular shell with a polyethylene liner, and inside of
11 that liner is a metal head. Inside of that metal head is another polyethylene
12 liner, which in turn captures a 22, 26, or 28 mm head that is attached to the
13 femoral stem. Thus, the Osteonics system has multiple polyethylene on metal
14 articulations. The multiple articulations generate polyethylene wear debris at a
15 much faster rate than designs with a single metal on polyethylene articulation.
16 Additionally, the range of motion only is approximately 90 degrees.

17 A constrained system developed by Zimmer, Inc. uses a metal shell with
18 a two-piece polyethylene liner. One piece is inserted into the acetabular metal
19 shell followed by placement of the other portion around the neck on the femoral
20 component before the femoral head has been put on the Morse taper. The head
21 is then reduced into the acetabular component. The polyethylene portion with a
22 metal band that is around the femoral neck is then brought into contact with the
23 acetabular polyethylene component and the metal band then secured to
24 "capture" the head within the assembled polyethylene liner. Again, this design
25 uses ultra high molecular weight polyethylene and can generate significant
26 debris as well as a limited range of motion. The limited range of motion results

1 in impingement in flexion, which generates a rotational torque at the bone shell
2 interface, potentially inhibiting bony in-growth into the acetabular shell.

3 In the late 1960's to early 1970's, others attempted to implant a
4 cemented conventional UHMWPE liner with greater than 50% head coverage.
5 Lagrange and Letournel, *Int Surg.* 60(1):21-4 (1975); Lanzetta, *Arch Ortop.*
6 83(1):49-53 (1970). These designs had a 35mm inner diameter and was
7 available in only two (47 and 58mm) outer diameters. These approaches,
8 however, did not yield a replacement with acceptable performance. Long-term
9 data is not available for the LaGrange/Letournel design, likely because it did
10 not become a widely-accepted product. Its head design (35 mm diameter) in
11 conjunction with conventional UHMWPE available at the time would have had
12 a substantial wear rate.

13 Thus, current and past designs have utilized various approaches,
14 including countersinks, in which the center of rotation of the femoral head is
15 below the level of the flat surface of the liner. Yet even the use of a
16 countersink design using large head diameters is less than optimal because,
17 among other things, these liners did not have an orifice that was less than the
18 diameter of the femoral head, and therefore have no mechanical capture, and
19 took no other steps to avoid or minimize dislocation.

20 It has been shown that larger heads are effective in reducing the rate of
21 recurrent dislocations, even when used with conventional polyethylene.
22 Amstutz *et al.*, 12th Annual International Symposium for Technology in
23 Arthroplasty, ISTA '99, Chicago, IL (1999). However, hip simulator studies
24 have shown that the wear of conventional polyethylene with the larger heads is
25 excessive. This disadvantage was demonstrated *in vivo* by the results of surface
26 replacement as well. Amstutz *et al.*, *Clin. Orthop.* 213: 92-114 (1986). In
27 addition, simply using a large head diameter does not produce mechanical
28 capture of the femoral head.

1 In achieving some of the advantages of the invention, in accordance with
2 one aspect of the invention, there are provided liners with one or more recesses.
3 The type of recesses according to the present invention, however, are different
4 than that of the unconstrained Modell St. Georg / Mark I & II and ENDO-
5 Modell liner, which was to "prevent irritation of the psoas muscle and enable(s)
6 removal of cement," rather than for reducing dislocation or impingement. See
7 Englebrecht E, Siegel A, Kluber D: The Modell St. Georg/Mark I/Mark II
8 Prosthesis. p. 66. In: Finerman G, Dorey F, Grigoris P, McKellop H (eds): Total
9 Hip Arthroplasty Outcomes. Churchill Livingstone, New York, 1998.

10 In view of the limitations of the commercialized designs, new
11 approaches are needed that would increase the inherent stability of the head-
12 liner articulation while at the same time increasing range of motion, which
13 would result in a decreased rate of dislocation for both primary and revision
14 total hip arthroplasties. Such approaches would decrease patient anxiety,
15 eliminate the need for postoperative dislocation precautions, and reduce the
16 number of revisions performed for dislocation and recurrent dislocation
17 resulting in a net cost savings to the healthcare system. Such risks of
18 dislocation are markedly reduced while range of motion is increased,
19 particularly when a large-head design and/or recesses are employed.

20 Cut away monopolar constrained acetabular liners (US Serial Nos.
21 60/222,049 and 60/234,345) for use in total hip replacement to help reduce the
22 potential of dislocation of the hip while still providing sufficient range of
23 motion for daily activities have been developed. The invention disclosed herein
24 also provides a separate constraining ring that can be used in conjunction with
25 the monopolar constrained acetabular liner and the cut away monopolar
26 constrained acetabular liner to provide additional support for the femoral head
27 to stay with the acetabular liner and avoid dislocation.

28

1
2 **Summary of the Invention**
3

4 It is an object of the invention to provide improved prostheses for use in
5 the hip. In accomplishing this and other objects, there is provided in
6 accordance with one aspect of the present invention a monopolar acetabular
7 liner that can enclose a femoral head to form a hip replacement prostheses,
8 wherein the liner has a rim that creates an orifice, and wherein the orifice has a
9 diameter that is smaller than the diameter of the femoral head. The rim extends
10 beyond the center line of the head (such as the center of rotation) when the head
11 is enclosed by the liner, and thereby the head is constrained from dislocation.
12 The liner can, in certain embodiments, include one or more recesses or cut-
13 aways to facilitate additional range of motion or be without recess or cut away
14 for use with liners that likewise lack a recess or cut away. The liner, in another
15 embodiment, is designed to accommodate proper fitting of a constraining ring
16 that can be used in conjunction with the monopolar constrained acetabular liner
17 and the cut away monopolar constrained acetabular liner. In accordance with
18 another embodiment, there is provided a constraining ring that can be used in
19 conjunction with the monopolar constrained acetabular liner and the cut away
20 monopolar constrained acetabular liner. The constraining rings provide
21 additional support for the femoral head to stay with the acetabular liner and
22 avoid dislocation. Preferably, the liner comprises ultra high molecular weight
23 polyethylene, that more preferably is all or in part cross-linked. Preferably, the
24 cross-linking is performed via irradiation. The femoral head can have a large
25 diameter. The constraining ring can, in certain embodiments, include one or
26 more recesses or cut-aways to be compatible with the corresponding liner.
27 Alternatively, the constraining ring will be without a recess or cut away for use
28 with liners that likewise lack a recess or cut away.

1 In accordance with another aspect of the present invention, there is
2 provided a monopolar acetabular assembly comprising (A) a monopolar
3 acetabular component that encloses a femoral head, wherein the liner has a rim
4 that creates an orifice, and wherein the orifice has a diameter that is smaller
5 than the diameter of the femoral head; and (B) a metal shell. The rim extends
6 beyond the center line of the head (such as the center of rotation) when the head
7 is enclosed by the liner, and thereby the head is constrained from dislocation.
8 The liner can, in certain embodiments, include one or more recesses or cut-
9 aways to facilitate additional range of motion or be without recess or cut away;
10 and a constraining ring which can be used in conjunction with the monopolar
11 constrained acetabular liner and the cut away monopolar constrained acetabular
12 liner to provide additional support for the femoral head to stay with the
13 acetabular liner and avoid dislocation. The constraining ring, which can be
14 made from a number of high strength materials (for example, cobalt chrome
15 alloy, titanium, stainless steel, etc.), is designed to fit around the perimeter of
16 the liner. The constraining ring, in another embodiment, is designed to fit
17 properly in conjunction with the monopolar constrained acetabular liner and the
18 cut away monopolar constrained acetabular liner. Preferably, the liner
19 comprises ultra high molecular weight polyethylene, that preferably is all or in
20 part cross-linked. Preferably, the cross-linking is performed via irradiation.
21 Preferably, the femoral head has a large diameter. The constraining ring can, in
22 certain embodiments, include one or more recesses or cut-aways to be
23 compatible with the corresponding liner. Alternatively, the constraining ring
24 will be without a recess or cut away for use with liners that likewise lack a
25 recess or cut away. In accordance with the invention, the constraining ring is
26 preferably made of high strength materials such as cobalt chrome alloy,
27 titanium, or stainless steel.

1 In accordance with still another aspect of the present invention, there is
2 provided a hip joint replacement assembly comprising (A) a monopolar
3 acetabular liner that encloses a femoral head, wherein the liner has a rim that
4 creates an orifice, and wherein the orifice has a diameter that is smaller than the
5 diameter of the femoral head; (B) a metal shell; and (C) a femoral head. The
6 rim extends beyond the center line of the head (such as the center of rotation)
7 when the head is enclosed by the liner, and thereby the head is constrained from
8 dislocation. The liner can, in certain embodiments, include one or more
9 recesses or cut-aways to facilitate additional range of motion or be without
10 recess or cut away; and a constraining ring which can be used in conjunction
11 with the monopolar constrained acetabular liner and the cut away monopolar
12 constrained acetabular liner to provide additional support for the femoral head
13 to stay with the acetabular liner and avoid dislocation. The constraining ring, in
14 another embodiment, is designed to fit properly in conjunction with the
15 monopolar constrained acetabular liner and the cut away monopolar constrained
16 acetabular liner. Preferably, the liner comprises ultra high molecular weight
17 polyethylene, that preferably is all or in part cross-linked. Preferably, the cross-
18 linking is performed via irradiation. The metal shell may be made of titanium,
19 stainless steel, or a cobalt chrome alloy. Preferably, the femoral head has a
20 large diameter. The constraining ring can, in certain embodiments, include one
21 or more recesses or cut-aways to be compatible with the corresponding liner.
22 Alternatively, the constraining ring will be without a recess or cut away for use
23 with liners that likewise lack a recess or cut away.

24 In accordance with the invention, metal shells preferably are made of
25 titanium, cobalt chrome alloys, or stainless steel. The femoral stems preferably
26 also may be made of a cobalt chrome alloys, stainless steel, or titanium.
27 Preferably, the femoral heads are made of a cobalt chrome alloys, stainless steel

1 or ceramic. Where the femoral head and stem are one piece, preferably they are
2 made of a cobalt chrome alloy or stainless steel.

3 In accordance with still a further aspect of the invention, there are
4 provided methods of replacing a hips in patients in need thereof, comprising the
5 step of surgically implanting in a given patient a monopolar acetabular liner
6 that can enclose a femoral head to form a hip replacement prostheses, wherein
7 the liner has a rim that creates an orifice, and wherein the orifice has a diameter
8 that is smaller than the diameter of the femoral head, and thereby the head is
9 constrained from dislocation. The liner can, in certain embodiments, include
10 one or more recesses or cut-aways to facilitate additional range of motion or be
11 without recess or cut away; and a constraining ring which can be used in
12 conjunction with the monopolar constrained acetabular liner and the cut away
13 monopolar constrained acetabular liner to provide additional support for the
14 femoral head to stay with the acetabular liner and avoid dislocation. The
15 constraining ring, in another embodiment, is designed to fit properly in
16 conjunction with the monopolar constrained acetabular liner and the cut away
17 monopolar constrained acetabular liner. Implantation of assemblies and total
18 replacements, such as shells, femoral heads and femoral stems, also are
19 provided.

20 In contrast to current bipolar and tripolar constrained components the
21 monopolar constrained design has: (i) increased range of motion, (ii) decreased
22 wear of the articulation, (iii) simpler intraoperative assembly, (iv) decreased
23 risk of impingement of the femoral neck upon the liner rim, (v) decreased stress
24 transfer to the acetabular component-cement interface, (vi) decreased stress
25 transfer to the cement-bone interface, (vii) decreased stress transfer to the metal
26 shell-bone interface, (viii) eliminates the thin polyethylene articulating surfaces
27 associated with multi-polar designs, (ix) eliminates multipolar locking rings,
28 which have had reported malfunctions and failure, (x) allows for the use of

1 large head diameters, (xi) has smaller possible acetabular shell outer diameters,
2 (xii) utilizes thicker polyethylene bearing surfaces, (xiii) and further facilitate
3 range of motion in preferred directions.

4 In contrast to the Legrance /Letournel design, the monopolar constrained
5 design according to the invention has: (i) a different and superior bearing
6 surface, (ii) larger head diameters, (iii) decreased wear, (iv) increased ROM, (v)
7 the capacity to be use in cemented or bony in-growth acetabular replacements,
8 (vi) thicker polyethylene bearing surfaces, (vii) modularity for use with
9 uncemented acetabular shells, (viii) can be easily exchanged at the time of
10 primary or revision surgery, and (ix) and can be designed to facilitate
11 movement in preferred directions.

12 Although large head diameters with standard UHMWPE bearing
13 surfaces have been used for the treatment of dislocation and recurrent
14 dislocation by Amstutz *et al.* In contrast to the designs employed by Amstutz,
15 the monopolar constrained has: (i) has a mechanical capture of the femoral
16 head, (ii) reduced wear, (iii) decreased periprosthetic osteolysis, (iv) modularity
17 for easy conversion between different amounts of constraint, and (v) can be
18 designed to facilitate movement in preferred directions.

19 In embodiments employing the recesses, the liner can have one or more
20 recess. A recess, often referred to herein as a cut away, can be positioned to
21 further facilitate movement in a desired direction.

22 Embodiments employing a constraining ring can be used in conjunction
23 with the monopolar constrained acetabular liner and the cut away monopolar
24 constrained acetabular liner to provide addition restraint against dislocation of
25 the hip joint while at same time not impeding the range of motion of the hip
26 joint. The constraining ring, in another embodiment, is designed to fit properly
27 in conjunction with the monopolar constrained acetabular liner and the cut
28 away monopolar constrained acetabular liner.

1 The constraining ring can be secured to the acetabular liner by means of
2 a number of locking mechanisms that are similar to those that are currently used
3 to secure acetabular liners into their mating metal acetabular shell.

4 Embodiments of this invention have used a locking mechanism which relies on
5 the spatial interference between the polyethylene acetabular liner and the metal
6 acetabular shell. This invention is not limited by the use of the locking
7 mechanism used in such embodiments and the use of other locking mechanisms
8 are possible.

9 In another embodiment of this invention have used a locking mechanism
10 which relies on the spatial interference between the polyethylene acetabular
11 liner and the metal constraining ring. As the constraining ring is being seated
12 onto the acetabular liner the polyethylene must deform as it moves past a ridge
13 on the constraining ring. Once the ring is fully seated then the deformed
14 polyethylene relaxes behind the ridge hence securing the constraining ring to
15 the liner. This invention is not limited by the use of the locking mechanism
16 used in such embodiments and the use of other locking mechanisms are
17 possible. Yet in another the constraining ring can also be fastened to the
18 acetabular liner by direct screw fixation where screws are passed directly
19 through the constraining ring into the polyethylene liner.

20 In another embodiment of this invention the constraining ring can be
21 secured to the liner by means of a retaining ring which is designed in an
22 unstressed state to sit in grooves in both the constraining ring and acetabular
23 liner. Upon setting the constraining ring onto the liner the retaining will deform
24 until the constraining ring is fully seated onto the liner at which point the
25 retaining ring relaxes into the designed grove in the liner.

26 The constraining ring can, in certain embodiments, include one or more
27 recesses or cut aways to be compatible with the corresponding liner.

1 Alternatively, the constraining ring will be without a recess or cut away for use
2 with liners that likewise lack a recess or cut away.

3 These and other aspects of the present invention will become apparent to
4 the skilled person in view of the description set forth below.

5 6 **Brief Description of the Figures**

7
8 Figure 1 is a schematic view of a monopolar liner in functional relation
9 with a femoral head and neck.

10 Figure 2 is a perspective view of a monopolar liner containing 2 recesses
11 to facilitate greater range of motion.

12 Figure 3 depicts the components of the cut away monopolar constrained
13 acetabular system with a constraining ring: metal acetabular shell (52) which is
14 secured to the acetabulum, polyethylene cut away monopolar constrained
15 acetabular liner (54), and constraining ring (56). Note the metal acetabular
16 shell is not essential for this invention as the acetabular liner can be directed
17 secured into the acetabulum with bone cement.

18 Figure 4 depicts constraining rings (56) in different perspectives.
19

20 **Detailed Description of Aspects of the Invention**

21
22 The present invention decreases the risk of dislocation of total hip
23 arthroplasty in both the primary and revision setting. See U.S. Serial No.
24 60/222,049, filed July 31, 2000, and U. S. Serial No. 60/234,345, filed
25 September 22, 2000, the entirety of which are hereby incorporated by reference.
26 In conjunction with large diameter femoral heads, such as disclosed in
27 PCT/US99/16070 (the entirety of which is hereby incorporated by reference),
28 the present invention can achieve a range of motion that is greater than is

1 currently available so called "constrained" systems using 22, 26, 28 and 32 mm
2 heads. A decrease in the rate of dislocation will have a positive effect on
3 patient satisfaction as well as hospital re-admission for treatment of dislocation.
4 The increased range of motion in this invention will afford patients a more
5 normal life style than the currently available constrained systems. The present
6 invention can be surgically implanted in a patient in the same or similar manner
7 as currently employed implants. Thus, the present invention results in an
8 improved quality of life as well as improved patient satisfaction.

9 The present invention advantageously employs UHMWPE liners,
10 preferably using UHMWPE that is cross-linked, including highly cross-linked
11 UHMWPE. UHMWPE can be cross-linked by a variety of approaches,
12 including those employing cross-linking chemicals and/or irradiation. Preferred
13 approaches for cross-linking employ irradiation, and are taught in
14 PCT/US97/02220, the entirety of which is hereby incorporated by reference.

15 According to the invention, there is preferably a two part acetabular
16 assembly, namely a metal shell for bony in-growth with UHMWPE liner,
17 preferably where the bearing surface of the liner that comes into contact with
18 the femoral head is comprised of crosslinked UHMWPE.

19 The liner of the present invention preferably is "monopolar" system.
20 The monopolar constrained acetabular preferably has a one piece design and
21 has a single metal to polyethylene articular surface, and thus preferably is not
22 bipolar or tripolar in design. The monopolar design allows for the use of
23 thicker polyethylene in the acetabular liner. Compared to the bipolar and
24 tripolar constrained/captured designs, the monopolar design decreases the
25 surface area of contact between metal and polyethylene because there is only
26 one metal-polyethylene articulation, rather than two or more found in other
27 designs. Moreover, the use of crosslinked UHMWPE will decrease the amount
28 of debris particles generated to articulation. Moreover, in the modular form of

1 this acetabular design, since the polyethylene component is not cemented into
2 place, some revision surgeries are more feasible. Moreover, with the modular
3 design different types of heads and liners can be used with the shell, and can be
4 selected by the surgeon during surgery.

5 According to one aspect of the invention, more than 50% of the volume
6 of the femoral head is enclosed within the polyethylene liner. The diameter of
7 the opening/orifice of the polyethylene liner is less than the diameter of the
8 femoral head that is inserted, as shown in Figure 1.

9 Figure 1 depicts at (10) a liner (12) in functional relation with a femoral
10 head (14) and neck (20). The rim surface (16) of the liner (12) extends beyond
11 the center line (18), representing the center of rotation of both the femoral head
12 and the acetabular liner. Preferably the liner rim surface is flat in this
13 embodiment. The inner portions of the rim circumscribe the orifice. If desired,
14 a metal shell, not pictured, would be positioned between the liner and the bone
15 at the mount site, and preferably is configured so as to promote in-growth of the
16 bone.

17 Figure 2 depicts at (30) a type of recessed or cut away liner (32). In the
18 pictured embodiment, the rim surface (34) is interrupted by two cut aways (36)
19 which permit greater range of motion while preserving a constraint to hold a
20 head in place by a snap fit. Region (38) shows that the rim surface (34) of the
21 liner (32) extends beyond the center line (not specifically depicted) in such a
22 manner that the opening/orifice of the liner (32) is less than the diameter of the
23 femoral head that is inserted therein. Thus, the inner portions of the rim
24 circumscribe the orifice in such a manner that the head is held within the liner.
25 If desired, a metal shell, not pictured, would be positioned between the liner
26 and the bone at the mount site, and preferably is configured so as to promote in-
27 growth of the bone.

1 The embodiments that employ one or more recesses can have the
2 recesses positioned to further facilitate movement in a desired direction. For
3 example, a liner might have a single recess to provide increased range of
4 motion in flexion. Another arrangement can be a liner with two recesses with
5 the second recess to provide increased range of motion in extension and/or
6 extension plus external rotation. Moreover, the increased range of motion
7 provided by the cut-away design also allows for greater tolerance for the
8 variations in the orientation of the acetabular component that can occur during
9 insertion.

10 As stated above, recesses can be positioned to further facilitate
11 movement in a desired direction, such as in the common directions of
12 impingement. Recesses can be placed in several different positions, but
13 preferentially would be placed in the position to produce the range of maximum
14 motion in a desired direction. For example, in a left hip, when looking at the
15 acetabular component in position and considering it to be the face of a clock,
16 the recess would be preferentially placed at about 1–2 o'clock. Under similar
17 circumstances one would place a recess for a right hip at about 10–11 o'clock.
18 Recesses in these positions assist with flexion alone and flexion plus internal
19 rotation. For embodiments with two or more recesses, at least one recess also
20 would be placed in the position to maximize extension alone and extension plus
21 external rotation, and thus these recesses would be placed at about 4-5 o'clock
22 in the left hip and about 7-8 o'clock in the right hip.

23 The recesses preferably are of sufficient size to accommodate the
24 femoral head and stem (including the neck), while still constraining the head
25 within the liner. The size of the recess in terms of width and depth depend
26 upon the size of the stem neck and the range of motion of motion sought, which
27 are readily determinable by the skilled person based upon a patient's size, age
28 and needs. If the liner is comprised of a cross-linked polymer, like irradiated

1 ultra high molecular weight polyethylene, then the recesses preferably are
2 machined into the liner. The liner, in another embodiment, is modified to
3 accommodate a constraining ring that can be used in conjunction with the
4 monopolar constrained acetabular liner and the cut away monopolar constrained
5 acetabular liner to provide additional support for the femoral head to stay with
6 the acetabular liner and avoid dislocation.

7 Figure 3 depicts at (50) a type of constraining ring (56). In the pictured
8 embodiment, showing components of the cut away monopolar constrained
9 acetabular system with a constraining ring: optional metal acetabular shell
10 which is secured to the acetabulum (52), polyethylene cut away monopolar
11 constrained acetabular liner (54), and the constraining ring (56). It is notable
12 that the metal acetabular shell is not essential for this invention as the
13 acetabular liner can be directed secured into the acetabulum with bone cement.
14 If desired, the metal shell (52), would be positioned between the liner and the
15 bone at the mount site, and preferably is configured so as to promote in-growth
16 of the bone.

17 Figure 4 depicts at (70) a constraining ring (56) shown in different
18 perspectives.

19 The opening in the monopolar constrained acetabular liner and the cut
20 away monopolar constrained acetabular liner through which the femoral head
21 passes upon reducing the femoral head into the liner is smaller than the femoral
22 head, which allows a snap-fit. Therefore, the constrained liner, which is
23 typically made of polyethylene, must deform slightly to allow the femoral head
24 to be embraced by the liner. The constraining ring, which can be made from a
25 number of high strength materials (for example, cobalt chrome alloy, titanium,
26 stainless steel, etc.), is designed to fit around the perimeter of the monopolar
27 constraining acetabular liner and is intended to serve as a structural support of

1 the liner to further ensure that the femoral head will stay within the acetabular
2 liner.

3 The constraining ring is circular in shape and has "cutouts" similar to
4 that of the cut away monopolar constrained acetabular liner (Figure 3 & 4).
5 This prevents the constraining ring from interfering with the range of motion of
6 the hip.

7 The constraining ring is preferably designed to be a single piece which
8 can be set onto the acetabular liner during the operative procedure after the
9 femoral head has been snap-fitted into the acetabular liner. This allows for the
10 femoral head to stay snapped within the constrained liner.

11 The constraining ring can, in certain embodiments, include one or more
12 recesses or cut-aways to be compatible with the corresponding liner.

13 Alternatively, the constraining ring will be without a recess or cut away for use
14 with liners that likewise lack a recess or cut away.

15 Gross sliding or micro motion between separate metallic surfaces of the
16 total hip components can generate wear debris which upon release into the joint
17 space can elicit a biological response that can lead to the development of
18 osteolysis and hence increasing the of potential of component loosening. The
19 design of the constraining ring and the acetabular liner are such that to prevent
20 contact between metallic surfaces. The constraining ring is designed to fit
21 properly in conjunction with the monopolar constrained acetabular liner and the
22 cut away monopolar constrained acetabular liner.

23 The components are designed such that the femoral neck will impinge
24 against the polyethylene liner and not the metallic constraining ring in all
25 directions of motion. Also, the constraining ring fastens directly to the
26 polyethylene acetabular liner and has no direct contact with the metal shell into
27 which the liner is set. Another advantage to this feature is that the use of the
28 constraining ring is not dependent on the use of a metal shell, hence allowing

1 this system to be used with an acetabular liner which is cemented directly into
2 the acetabulum.

3 The constraining ring (see Figures 3 & 4) can be secured to the
4 acetabular liner by means of a number of locking mechanisms which are
5 currently used to secure acetabular liners into their mating metal acetabular
6 shell. Embodiments of this invention have used a locking mechanism which
7 relies on the spatial interference between the polyethylene acetabular liner and
8 the metal acetabular shell. This invention is not limited by the use of the
9 locking mechanism used in such embodiments and the use of other locking
10 mechanisms are possible.

11 In another embodiment of this invention have used a locking mechanism
12 which relies on the spatial interference between the polyethylene acetabular
13 liner and the metal constraining ring. As the constraining ring is being seated
14 onto the acetabular liner the polyethylene must deform as it moves past a ridge
15 on the constraining ring. Once the ring is fully seated then the deformed
16 polyethylene relaxes behind the ridge hence securing the constraining ring to
17 the liner. This invention is not limited by the use of the locking mechanism
18 used in such embodiments and the use of other locking mechanisms are
19 possible and contemplated by the invention.

20 Yet in another the constraining ring can also be fastened to the
21 acetabular liner by direct screw fixation where screws are passed directly
22 through the constraining ring into the polyethylene liner.

23 In another embodiment of this invention the constraining ring can be
24 secured to the liner by means of a retaining ring which is designed in an
25 unstressed state to sit in grooves in both the constraining ring and acetabular
26 liner. Upon setting the constraining ring onto the liner the retaining will deform
27 until the constraining ring is fully seated onto the liner at which point the
28 retaining ring relaxes into the designed grove in the liner.

1 The constraining ring can, in certain embodiments, include one or more
2 recesses or cut-aways to be compatible with the corresponding liner.
3 Alternatively, the constraining ring will be without a recess or cut away for use
4 with liners that likewise lack a recess or cut away.

5 Description of the Assembly of Cut Away Monopolar Constrained
6 Acetabular Liner with Constraining Ring (see Figure 3): Components of the cut
7 away monopolar constrained acetabular system consisting of: i) metal
8 acetabular shell which is secured to the acetabulum, ii) polyethylene cut away
9 monopolar constrained acetabular liner, and iii) constraining ring. The metal
10 acetabular shell is not essential for this invention as the acetabular liner can be
11 directed secured into the acetabulum with bone cement. The cut away
12 monopolar constrained acetabular liner is set into the metal acetabular. The
13 constraining ring is placed over the femoral component and the femoral head is
14 snap-fitted into the acetabular liner. The constraining ring is then set onto the
15 cut away monopolar constraining acetabular liner with the cutouts of the
16 constraining ring aligned with the cutouts of the acetabular liner.

17 Demonstration of the Position of the Acetabular Component within the
18 Hip and Range of Motion: The actual position of the acetabular component
19 within the hip will be set during the operative procedure and will depend on the
20 patient's anatomy and gait. The cut away portion of the acetabular component
21 allows for sufficient range of motion in flexion. The cut away portion of the
22 acetabular component allows for sufficient internal rotation at 90° of flexion.
23 The cut away portion of the acetabular component allows for sufficient external
24 rotation at neutral flexion.

25 In any of the embodiments of the invention, the liners of the invention
26 can be used with hemispherical and non-hemispherical acetabular shells.

27 Also, the invention can be used with any head diameter, including large
28 head diameters (for example, 35 mm or greater, such as 38 mm, 40 mm, 42

1 mm, 44 mm, and any diameter in between or larger) in order to increase the
2 range of motion in comparison with currently available constrained systems.

3 The invention is further demonstrated by the following example, which
4 do not limit the invention in any manner.

5
6 **Example 1**
7

8 The load required for insertion and dislocation of femoral heads in a
9 constrained liner according to the invention was quantified by inserting 32 and
10 38 mm heads into simulated liners of electron beam crosslinked UHMWPE.
11 Two and three dimensional modeling was performed to assess ROM and
12 stability *in vitro*. The liner had no chamfer.

13 The ROM, and the loads required for insertion and dislocation using
14 different opening diameters for 32 mm and 38 mm heads in simulated
15 monopolar liners were measured. A 32 mm head with a 31 mm liner opening
16 required 60 lbs. for insertion and 55 lbs. for dislocation. When the opening was
17 increased to 31.5 mm the forces for insertion and dislocation decreased to 29
18 lbs., and 24 lbs., respectively. Testing of 35.5 mm, 36.5 mm, and 37.5 mm
19 openings with a 38 mm head was performed. The insertional loads were 157,
20 130, and 28 lbs. The force necessary to produce dislocation of the femoral head
21 were 135, 126, and 28 lbs., respectively.

22 The ROM for the 38 mm head and a 35.5mm orifice liner is 110°. This
23 increases to 118° and 131° as the orifice diameter is increased to 36.5 and 37.5
24 mm. The 32 mm head and 31 mm orifice liner has 116° ROM. The ROM
25 increases to 124° when a 31.5 mm orifice is used with the 32 mm head.

26 These data demonstrate that the constrained design according to the
27 invention can minimize the occurrence of dislocation, even with heads and
28 liners that are constructed to permit enhanced range of movement.

1 It is to be understood that the description, specific examples and data,
2 while indicating exemplary embodiments, are given by way of illustration and
3 are not intended to limit the present invention. Various changes and
4 modifications within the present invention will become apparent to the skilled
5 artisan from the discussion, disclosure and data contained herein, and thus are
6 considered part of the invention.

7

8

What is claimed is:

1. A monopolar acetabular liner that can enclose a femoral head to form a hip replacement prostheses, wherein the liner has a rim that creates an orifice, and wherein the orifice has a diameter that is smaller than the diameter of the femoral head.
2. The liner according to claim 1, wherein the rim extends beyond the center line of the head when the head is enclosed by the liner.
3. The liner according to claim 1, wherein the liner comprises polyethylene.
4. The liner according to claim 3, wherein comprises ultra high molecular weight polyethylene.
5. The liner according to claim 4, wherein ultra high molecular weight polyethylene is cross-linked.
6. The liner according to claim 5, wherein the cross-linking is performed via irradiation.
7. The liner according to claim 1, wherein the femoral head has a large diameter.
8. The liner according to claim 1, wherein the liner has at least one recess.
9. A monopolar acetabular assembly comprising
 - (A) a monopolar acetabular liner that encloses a femoral head, wherein the liner has a rim that creates an orifice, and wherein the orifice has a diameter that is smaller than the diameter of the femoral head; and
 - (B) a metal shell.
10. The assembly according to claim 9, wherein the rim extends beyond the center line of the head when the head is enclosed by the liner.
11. The assembly according to claim 9, wherein the metal shell is made of titanium or chrome cobalt .

12. The assembly according to claim 9, wherein the femoral head has a large diameter.
13. The assembly according to claim 9, wherein the liner has at least one recess.
14. A hip joint replacement assembly comprising
 - (A) a monopolar acetabular liner that encloses a femoral head, wherein the liner has a rim that creates an orifice, and wherein the orifice has a diameter that is smaller than the diameter of the femoral head;
 - (B) a metal shell; and
 - (C) a femoral head.
15. The replacement assembly according to claim 14, wherein the femoral head is integral with or modular on a femoral stem.
16. The replacement assembly according to claim 14, wherein the femoral head is made of a cobalt chrome alloy, stainless steel, or ceramic.
17. The replacement assembly according to claim 15, wherein the femoral stem is made of a cobalt chrome alloy, stainless steel, or titanium.
18. The replacement assembly according to claim 14, wherein the rim extends beyond the center line of the head when the head is enclosed by the liner.
19. The replacement assembly according to claim 14, wherein the metal shell is made of titanium, stainless steel, or a cobalt chrome alloy.
20. The replacement assembly according to claim 14, wherein the femoral head has a large diameter.
21. The replacement assembly according to claim 14, wherein the liner has at least one recess.
22. A method of replacing a hip in a patient in need thereof, comprising the step of surgically implanting in a patient a monopolar acetabular liner or monopolar component that can enclose a femoral head to form a hip replacement prostheses, wherein the liner has a rim that creates an orifice,

and wherein the orifice has a diameter that is smaller than the diameter of the femoral head.

23. The method according to claim 22, wherein a metal shell also is implanted.
24. The method according to claim 22, wherein a femoral head and stem also are implanted.
25. The method according to claim 22, wherein the rim extends beyond the center line of the head when the head is enclosed by the liner.
26. The method according to claim 22, wherein the liner comprises ultra high molecular weight polyethylene.
27. The method according to claim 26, wherein ultra high molecular weight polyethylene is cross-linked.
28. The method according to claim 27, wherein the cross-linking is performed via irradiation.
29. The method according to claim 22, wherein the femoral head has a large diameter.
30. The method according to claim 22, wherein the liner has at least one recess.
31. A monopolar acetabular liner that can enclose a femoral head to form a hip replacement prostheses, wherein the liner has a rim that creates an orifice and the liner has at least one recess, and wherein the orifice has a diameter that is smaller than the diameter of the femoral head.
32. The monopolar acetabular liner according to claim 31, wherein the liner has at least two recesses.
33. A monopolar acetabular assembly comprising
 - (A) a monopolar acetabular liner that encloses a femoral head, wherein the liner has a rim that creates an orifice and the liner has at least one recess, and wherein the orifice has a diameter that is smaller than the diameter of the femoral head; and
 - (B) a metal shell.

34. The monopolar acetabular assembly according to claim 33, wherein the liner has at least two recesses.
35. A hip joint replacement assembly comprising:
- (A) a monopolar acetabular liner that encloses a femoral head, wherein the liner has a rim that creates an orifice and the liner has at least one recess, and wherein the orifice has a diameter that is smaller than the diameter of the femoral head;
 - (B) a metal shell; and
 - (C) a femoral head.
36. The hip joint assembly according to claim 35, wherein the liner has at least two recesses.
37. A method of replacing a hip in a patient in need thereof, comprising the step of surgically implanting in a patient a monopolar acetabular liner or monopolar component that can enclose a femoral head to form a hip replacement prostheses, wherein the liner has a rim that creates an orifice and the liner has at least one recess, and wherein the orifice has a diameter that is smaller than the diameter of the femoral head.
38. The method according to claim 37, wherein the liner has at least two recesses.
39. A constraining ring that is used in conjunction with a monopolar constrained acetabular liner or a cut away monopolar constrained acetabular liner, wherein the ring fits around the perimeter of the monopolar constrained acetabular liner, and wherein the ring is set onto the acetabular liner during the operative procedure after the femoral head is reduced into the acetabular liner.
40. The constraining ring according to claim 39, wherein the shape of the ring is circular.

41. The constraining ring according to claim 39, wherein the ring is made of high strength materials such as cobalt chrome alloy, titanium, or stainless steel.
42. The constraining ring according to claim 39, wherein the ring is a single piece.
43. The constraining ring according to claim 39, has no recess.
44. The constraining ring according to claim 39, has at least one recess.
45. The constraining ring according to claim 39, has at least two recesses.
46. The liner according to claim 39, has no recess.
47. The liner according to claim 39, has at least one recess.
48. The liner according to claim 39, has at least two recesses.
49. A monopolar constrained acetabular liner system with constraining ring assembly comprising:
- (A) a monopolar acetabular liner that encloses a femoral head, wherein the liner has a rim that creates an orifice, wherein the orifice has a diameter that is smaller than the diameter of the femoral head, wherein a constraining ring fits around the perimeter of the monopolar constrained acetabular liner, wherein the constraining ring is set onto the acetabular liner during the operative procedure after the femoral head is reduced into the acetabular liner; and
 - (B) a metal shell.
50. The assembly according to claim 49, wherein the constraining ring fastens directly to the polyethylene acetabular liner and has no direct contact with the metal shell into which the liner is set.
51. The assembly according to claim 49, wherein the constraining ring is not dependent on the use of a metal shell hence allowing this system to be used with an acetabular liner which is cemented directly into the acetabulum.

52. The assembly according to claim 49, wherein the constraining ring can be secured to the acetabular liner by means of a number of locking mechanisms.
53. The assembly according to claim 49, wherein the shape of the constraining ring is circular.
54. The assembly according to claim 49, wherein the constraining ring is made of high strength materials such as cobalt chrome alloy, titanium, or stainless steel.
55. The assembly according to claim 49, wherein the constraining ring is a single piece.
56. The assembly according to claim 49, wherein the constraining ring has no recess.
57. The assembly according to claim 49, wherein the constraining ring has at least one recess.
58. The assembly according to claim 49, wherein the constraining ring has at least two recesses.
59. The assembly according to claim 49, wherein the liner has no recess.
60. The assembly according to claim 49, wherein the liner has at least one recess.
61. The assembly according to claim 49, wherein the liner has at least two recesses.
62. A hip joint replacement assembly comprising:
- (A) a monopolar acetabular liner that encloses a femoral head, wherein the liner has a rim that creates an orifice, wherein the orifice has a diameter that is smaller than the diameter of the femoral head, wherein a constraining ring fits around the perimeter of the monopolar constrained acetabular liner, wherein the constraining ring is set onto the

acetabular liner during the operative procedure after the femoral head is reduced into the acetabular liner;

(B) a metal shell; and

(C) a femoral head.

63. The hip joint assembly according to claim 62, wherein the constraining ring fastens directly to the polyethylene acetabular liner and has no direct contact with the metal shell into which the liner is set.
64. The hip joint assembly according to claim 62, wherein the constraining ring is not dependent on the use of a metal shell hence allowing this system to be used with an acetabular liner which is cemented directly into the acetabulum.
65. The hip joint assembly according to claim 62, wherein the constraining ring can be secured to the acetabular liner by means of a number of locking mechanisms.
66. The hip joint assembly according to claim 62, wherein the shape of the constraining ring is circular.
67. The hip joint assembly according to claim 62, wherein the constraining ring is made of high strength materials such as cobalt chrome alloy, titanium, or stainless steel.
68. The hip joint assembly according to claim 62, wherein the constraining ring is a single piece.
69. The hip joint assembly according to claim 62, wherein the constraining ring has no recess.
70. The hip joint assembly according to claim 62, wherein the constraining ring has at least one recess.
71. The hip joint assembly according to claim 62, wherein the constraining ring has at least two recesses.

72. The hip joint assembly according to claim 62, wherein the liner has no recess.
73. The hip joint assembly according to claim 62, wherein the liner has at least one recess.
74. The hip joint assembly according to claim 62, wherein the liner has at least two recesses.
75. A method of replacing a hip in a patient in need thereof, comprising the step of surgically implanting in a patient a monopolar acetabular liner or monopolar component that can enclose a femoral head to form a hip replacement prostheses, wherein the liner has a rim that creates an orifice, wherein the orifice has a diameter that is smaller than the diameter of the femoral head, wherein a constraining ring is used with the monopolar constrained acetabular liner or a cut away monopolar constrained acetabular liner, wherein the constraining ring fits around the perimeter of the constrained acetabular liner, wherein the constraining ring can be set onto the acetabular liner during the operative procedure after the femoral head is reduced into the acetabular liner.
76. The method according to claim 75, wherein the constraining ring fastens directly to the polyethylene acetabular liner and has no direct contact with the metal shell into which the liner is set.
77. The method according to claim 75, wherein the constraining ring is not dependent on the use of a metal shell hence allowing this system to be used with an acetabular liner which is cemented directly into the acetabulum.
78. The method according to claim 75, wherein the constraining ring can be secured to the acetabular liner by means of a number of locking mechanisms.
79. The method according to claim 75, wherein the shape of the constraining ring is circular.

80. The method according to claim 75, wherein the constraining ring is made of high strength materials such as cobalt chrome alloy, titanium, or stainless steel.
81. The method according to claim 75, wherein the constraining ring is a single piece.
82. The method according to claim 75, wherein the constraining ring has no recess.
83. The method according to claim 75, wherein the constraining ring has at least one recess.
84. The method according to claim 75, wherein the constraining ring has at least two recesses.
85. The method according to claim 75, wherein the liner has no recess.
86. The method according to claim 75, wherein the liner has at least one recess.
87. The method according to claim 75, wherein the liner has at least two recesses.
88. A cut away monopolar constrained acetabular liner system with constraining ring assembly comprising: a monopolar acetabular liner that encloses a femoral head, wherein the liner has a rim that creates an orifice, wherein the orifice has a diameter that is smaller than the diameter of the femoral head, wherein a constraining ring is used with the monopolar constrained acetabular liner or the cut away monopolar constrained acetabular liner, wherein the constraining ring fits around the perimeter of the constrained acetabular liner, and wherein the constraining ring is set onto the acetabular liner during the operative procedure after the femoral head is reduced into the acetabular liner.
89. The assembly according to claim 88, wherein the constraining ring fastens directly to the polyethylene acetabular liner.

90. The assembly according to claim 88, wherein the constraining ring is not dependent on the use of a metal shell hence allowing this system to be used with an acetabular liner which is cemented directly into the acetabulum.
91. The assembly according to claim 88, wherein the constraining ring can be secured to the acetabular liner by means of a number of locking mechanisms.
92. The assembly according to claim 88, wherein the shape of the constraining ring is circular.
93. The assembly according to claim 88, wherein the constraining ring is made of high strength materials such as cobalt chrome alloy, titanium, or stainless steel.
94. The assembly according to claim 88, wherein the constraining ring is a single piece.
95. The assembly according to claim 88, wherein the constraining ring has no recess.
96. The assembly according to claim 88, wherein the constraining ring has at least one recess.
97. The assembly according to claim 88, wherein the constraining ring has at least two recesses.
98. The assembly according to claim 88, wherein the liner has no recess.
99. The assembly according to claim 88, wherein the liner has at least one recess.
100. The assembly according to claim 88, wherein the liner has at least two recesses.
101. A hip joint replacement assembly comprising:
(A) a monopolar acetabular liner that encloses a femoral head, wherein the liner has a rim that creates an orifice, wherein the orifice has a diameter that is smaller than the diameter of the femoral head, wherein

a constraining ring fits around the perimeter of the monopolar constrained acetabular liner, wherein the constraining ring is set onto the acetabular liner during the operative procedure after the femoral head is reduced into the acetabular liner; and

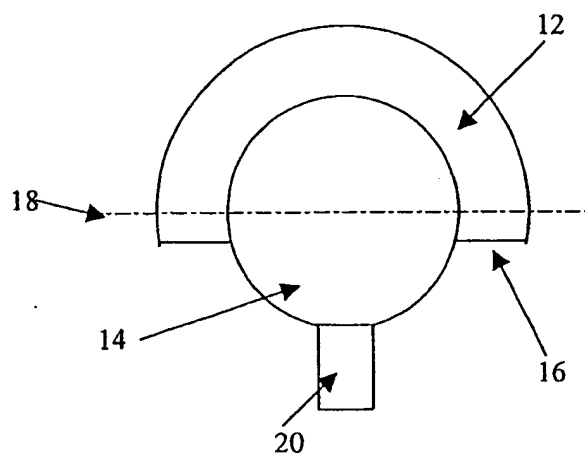
(B) a femoral head.

102. The hip joint assembly according to claim 101, wherein the constraining ring fastens directly to the polyethylene acetabular liner.
103. The hip joint assembly according to claim 101, wherein the constraining ring is not dependent on the use of a metal shell hence allowing this system to be used with an acetabular liner which is cemented directly into the acetabulum.
104. The hip joint assembly according to claim 101, wherein the constraining ring can be secured to the acetabular liner by means of a number of locking mechanisms.
105. The hip joint assembly according to claim 101, wherein the shape of the constraining ring is circular.
106. The hip joint assembly according to claim 101, wherein the constraining ring is made of high strength materials such as cobalt chrome alloy, titanium, or stainless steel.
107. The hip joint assembly according to claim 101, wherein the constraining ring is a single piece.
108. The hip joint assembly according to claim 101, wherein the constraining ring has no.
109. The hip joint assembly according to claim 101, wherein the constraining ring has at least one recess.
110. The hip joint assembly according to claim 101, wherein the constraining ring has at least two recesses.

111. The hip joint assembly according to claim 101, wherein the liner has no recess.
112. The hip joint assembly according to claim 101, wherein the liner has at least one recess.
113. The hip joint assembly according to claim 101, wherein the liner has at least two recesses.
114. A method of replacing a hip in a patient in need thereof, comprising the step of surgically implanting in a patient a monopolar acetabular liner or monopolar component that can enclose a femoral head to form a hip replacement prostheses, wherein the liner has a rim that creates an orifice, wherein the orifice has a diameter that is smaller than the diameter of the femoral head, wherein a constraining ring is used with a monopolar constrained acetabular liner or a cut away monopolar constrained acetabular liner, wherein the constraining ring fits around the perimeter of the constrained liner, wherein the constraining ring can be set onto the acetabular liner during the operative procedure after the femoral head is reduced into the acetabular liner.
115. The method according to claim 114, wherein the constraining ring fastens directly to the polyethylene acetabular liner.
116. The method according to claim 114, wherein the constraining ring is not dependent on the use of a metal shell hence allowing this system to be used with an acetabular liner which is cemented directly into the acetabulum.
117. The method according to claim 114, wherein the constraining ring can be secured to the acetabular liner by means of a number of locking mechanisms.
118. The method according to claim 114, wherein the shape of the constraining ring is circular.

119. The method according to claim 114, wherein the constraining ring is made of high strength materials such as cobalt chrome alloy, titanium, or stainless steel.
120. The method according to claim 114, wherein the constraining ring is a single piece.
121. The method according to claim 114, wherein the constraining ring has no recess.
122. The method according to claim 114, wherein the constraining ring has at least one recess.
123. The method according to claim 114, wherein the constraining ring has at least two recesses.
124. The method according to claim 114, wherein the liner has no recess.
125. The method according to claim 114, wherein the liner has at least one recess.

FIGURE 1

10

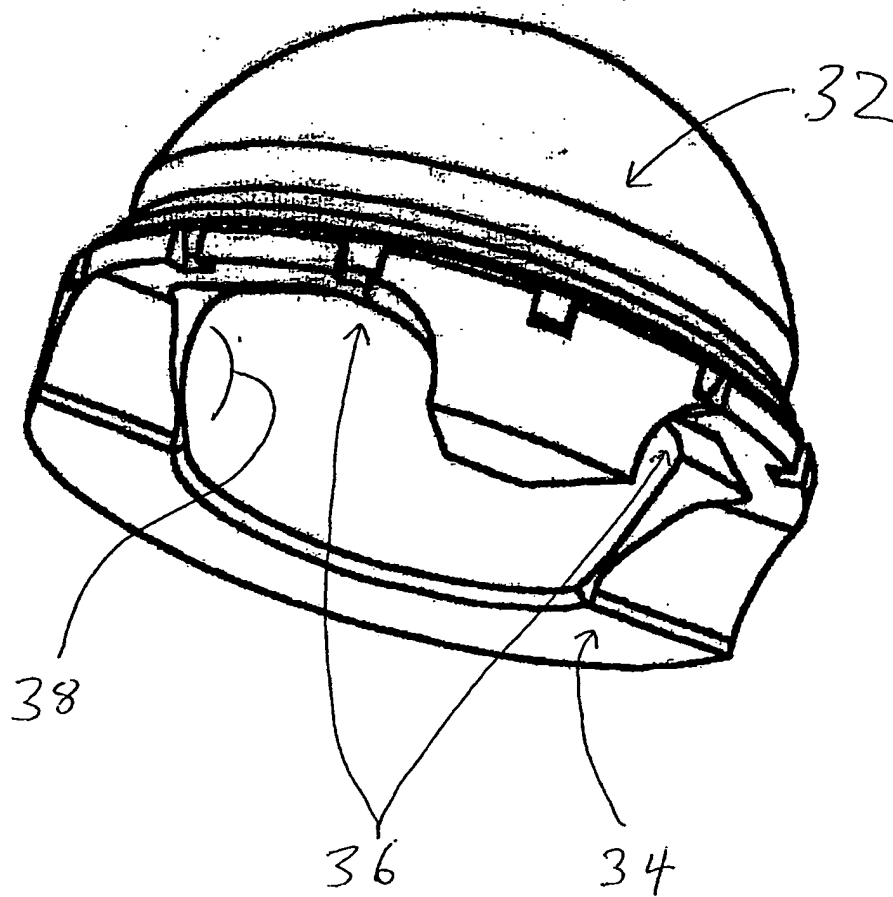


FIGURE 2

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FIGURE 3
50

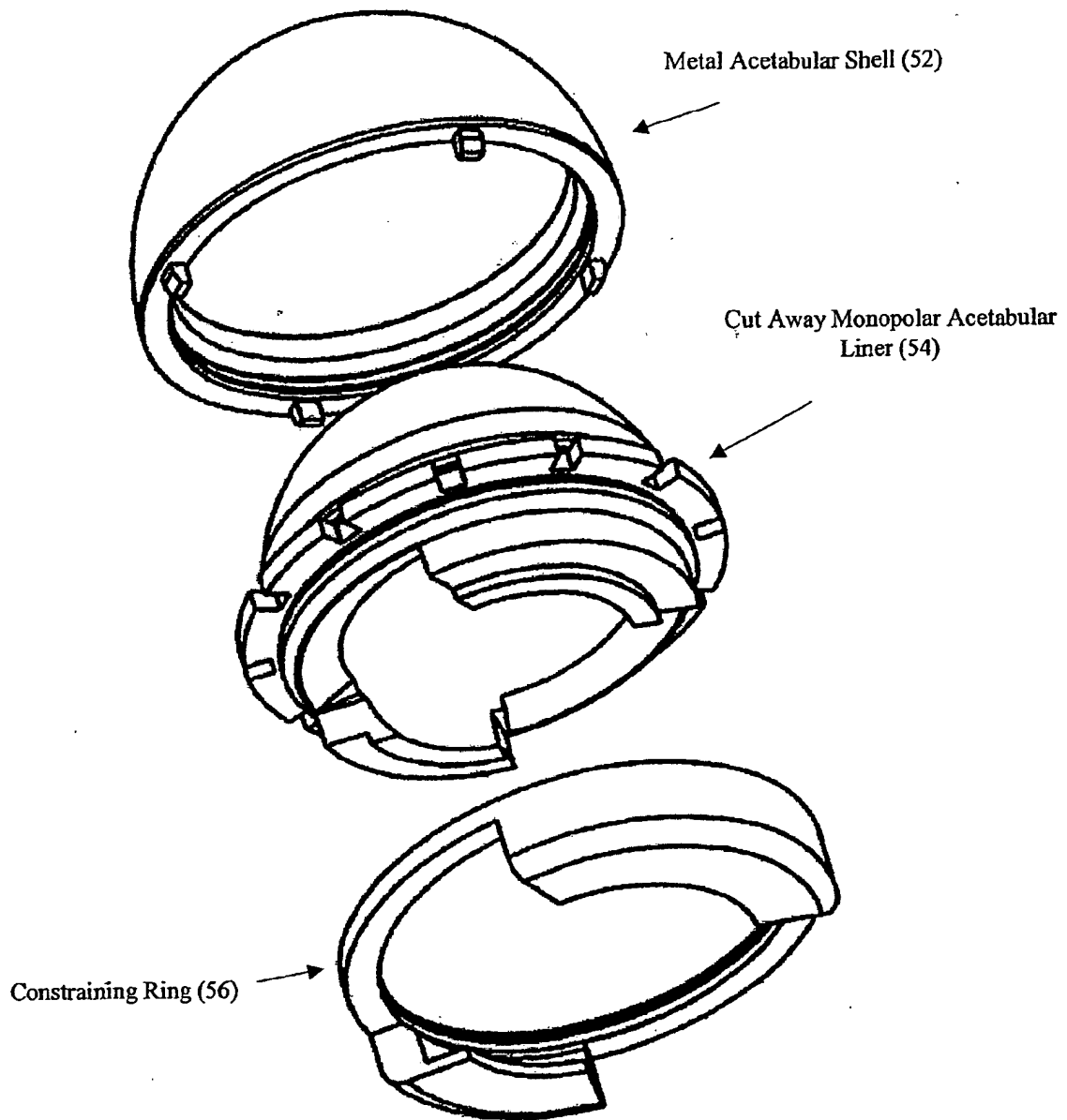


FIG. 3

FIGURE 4

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